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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/609,120	06/27/2003	Wing Ming Keung	11187-00016	6701
27716	7590	04/24/2006	EXAMINER	
CV THERAPEUTICS, INC. 3172 PORTER DRIVE PALO ALTO, CA 94304			OWENS, AMELIA A	
			ART UNIT	PAPER NUMBER
			1625	
DATE MAILED: 04/24/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/609,120	KEUNG ET AL.	
	Examiner	Art Unit	
	Amelia A. Owens	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) ____ is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 7-9, 12-16 and 26-30 is/are allowed.
- 6) ☒ Claim(s) 7-9, 12-14, 16 and 26-28 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

1. Claims 1-6,10,11,17-25,31,32 have been canceled. Claims 7-9,12-16,26-30 are pending.

Claim Rejections - 35 USC § 112

2. The rejection of claims 7-25 under 35 USC 112, 2nd paragraph has been dropped as claims have been canceled and/or amended.
3. The rejection of claims 1-32 under 35 USC 112, 1st paragraph has been dropped as claims have been canceled and/or amended.
4. Claims 7-9,12-14,16,26-28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the many of the R1 and R3 variables, does not reasonably provide enablement for compounds where R1 ends in '-oxy' such as -alkoxy--, and the result is a peroxy linkage; *AND* for compounds where R3 is 'sugar'. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

In the pharmaceutical area, declarations under 37 CFR 1.132 are often employed to set forth the advantage of a particular substituent. The definition and claiming of substituents is extremely important in the claims of the application. Applicant should not be able to preempt future work of others by means of claims to compounds they themselves did not make and test.

Applicants are claiming a compound of the formula. Pure chemistry, a compound. That compound used for any purpose is taken from the public in a 20 year monopoly by applicants. Then, the public is entitled to know what compound they cannot use. The public cannot tell what they may not use.

As applied to pure compounds, in re Cavallito and Gray, 134 USPQ 370, and in re Sus and Schaefer, 134 USPQ 301, are considered to set the proper applicable standard of required definiteness and support.

5. Claims 7-9,12-14,16,26-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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With regard to compounds where R1 forms a *peroxy*; and to compounds where R3 is *sugar* - the written description is considered inadequate here in the specification. Applicant should, in return for a 20 year monopoly, be disclosing to the public that which they know as an actual demonstrated fact. The disclosure should not be merely an invitation to experiment. If you (the public) find that it works, I claim it, is not a proper basis of patentability. In re Kirk, 153 USPQ 48 at page 53.

6. For above paragraphs 5,6 - claims 15,29,30 are not included as R1 is defined such that a peroxy group is not formed.

Claim Rejections - 35 USC § 102

7. Claims 27,28 are rejected under 35 U.S.C. 102(b) as being anticipated by Shao et al (CA 94:174809) that teach species according to the invention. See RN 77316-82-6. Note R1 is heterocyclcarbonyl.

8. Claims 27,28 are rejected under 35 U.S.C. 102(b) as being anticipated by Lei et al that teach species according to the invention. See formula I. Note R1 is hydrogen; R5 is alkyl.

9. Claims 27,28 are rejected under 35 U.S.C. 102(b) as being anticipated by Zhou et al that teach species according to the invention. See formula I and definitions for R1. Note R5 may be methoxy (alkoxy). R1 may haloalkylcarbonyl for example. Other species are depicted.

10. Claims 27,28 are rejected under 35 U.S.C. 102(b) as being anticipated by Tseng et al that teach species according to the invention. See formula I, where R/R1 are hydrogen.

11. Claims 27,28 are rejected under 35 U.S.C. 102(b) as being anticipated by Diedrich that teach species according to the invention. See formula IV @ page 449; note R/R1/R2 all hydrogen; and R3 is OCH₃.

12. Claims 27,28 are rejected under 35 U.S.C. 102(b) as being anticipated by Feuer et al (USP 3907830) that teach species according to the invention. See column 8 formula V, VI.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 26,27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Feuer et al (USP 4166862) and Feuer et al (USP 3907830).

Feuer et al '862 generically disclose isoflavone compounds as are instantly claimed and their use as animal feed additives. See column 2 lines 30-58, formula II. Note R2/R3/R4 are hydrogen and R5 is (un)saturated alkyl that may be substituted and salts thereof.

One of ordinary skill in the art would thus be motivated to prepare compounds from under the Feuer et al genus in order to obtain additional animal feed additives.

Also, one of ordinary skill in the art would be motivated to prepare compounds structurally similar to those of Feuer et al in the expectation of obtaining a compound useful as animal feed additives as compounds structurally similar in structure are expected to have similar properties. The level of skill in the art is further reflected in *In re Lohr* 137 USPQ 548 at 549 (CCPA 1963), and in *In re Payne* 204 USPQ 249 at 254 (CCPA 1979).

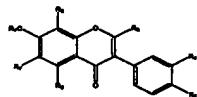
Feuer et al also generically disclose isoflavone compounds of formula IV @ column 3 lines 13-35. Note R6 may be substituted alkyl, hydrogen, or acyl. The sole difference is a –OH at the R3 position instead of a hydrogen.

Motivation for one of ordinary skill in the art to replace the –OH with a hydrogen arises as Feuer teach isoflavones compounds that have both a hydrogen and an OH at the 3-position. Further motivation arises as compounds structurally similar in structure are expected to have similar properties. No unexpected or unobvious results are noted.

14. Claims 28-30 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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Allowable Subject Matter



Compounds according to the above formula where R2/R3/R4/R5/R6/R7 are as defined and R1 is amino; alkoxycarbonyl; carboxy -C(O)H; cycloalkylcarbonyl.

Compounds according to the above formula where R2/R3/R4/R5/R6/R7 are as defined and R1 is heterocyclcarbonyl and the heterocycles are those listed in the specification at page 5 with the exception of pyridyl. See CA 94:174809 that depicts a pyridyl species.

Claims 7-9,12-16 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amelia A. Owens whose telephone number is 571-272-0690. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia J. Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Amelia A. Owens', is written over a horizontal line.

Amelia A. Owens
Primary Examiner
Art Unit 1625